SECTION 11

510(k) Summary

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

NOV 14 2006

Contact Person: Sheila W. Pickering
Telephone: (650) 943 7187
Fax: (650) 943 7053

Submission Date: October 06, 2006

Device Name: Siemens Acuson Sequoia Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:
Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 74-DQO

A. Legally Marketed Predicate Devices
The Siemens Acuson Sequoia ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product the Siemens Acuson Sequoia ultrasound system (K052410).

B. Device Description:

The Siemens Acuson Sequoia has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Sequoia ultrasound imaging system is intended for use in the following applications:

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid and penis), Neonatal/Adult Cephalic, Cardiac (adult, pediatric and neonatal), Transesophageal, Transrectal, Transvaginal, Peripheral Vessels, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.
The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The Sequoia modifications are verified and validated according to the company's design control process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2006

Sheila Pickering, Ph.D.
Senior Director of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
1230 Shorebird Way
MOUNTAIN VIEW CA 94039

Re: K063085
Trade Name: ACSON Sequoia™ Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: IYO, IYN, ITX, and DQO
Dated: October 6, 2006
Received: October 16, 2006

Dear Dr. Pickering:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACSON Sequoia™ Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C1	9L4	4V1
5C2	13L5SP	4V1c
6C2	15L8	4V2
8C4	15L8w	5V2c
EC10c5	17L5	7V3c
EV8C4	V5M TEE	8V3
6L3	V7M TEE	8V5
8L5	V7B TEE	10V4
8L5T	3V2c	AUX CW

AcuNav (IC10V5 or 10F) Ultrasound Catheter
AcuNav 8F Ultrasound Catheter

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang at (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K063085

Device Name: ACUSON Sequoia™ Ultrasound System

Indications for Use:

The Sequoia ultrasound imaging system is intended for use in the following applications:

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid and penis), Neonatal/Adult Cephalic, Cardiac (adult, pediatric and neonatal), Transesophageal, Transrectal, Transvaginal, Peripheral Vessels, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **Sequoia™ Ultrasound System**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic		P	P	P	P	P	P		P*	P
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal		P	P	P	P	P	P		P*	P
Transvaginal		P	P	P	P	P	P		P*	P
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, #K992631, #K992580, #K973767, #K935595/S1.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: 4C1

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, and #K002807.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: 5C2

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **6C2**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, and #K002807.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **8C4**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **EC10c5**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P	P	P	P		P*	P
Transvaginal		P	P	P	P	P	P		P*	P
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, and #K002807.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **EV8C4**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P	P	P	P		P*	P
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **6L3**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric										
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: 8L5

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric										
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **8L5T**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **9L4**

Indications for Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		N	N	N		N	N	N	N*	N
Abdominal										
Intraoperative Abdominal		N	N	N		N	N	N	N*	N
Intraoperative Neurological		N	N	N		N	N	N	N*	N
Pediatric		N	N	N		N	N	N	N*	N
Small Organ (specify)**		N	N	N		N	N	N	N*	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N	N	N		N	N	N	N*	N
Laparoscopic										
Musculo-skeletal (Conventional)		N	N	N		N	N	N	N*	N
Musculo-skeletal (Superficial)		N	N	N		N	N	N	N*	N
Other (specify)***										

N=New Indication

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **13L5SP**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **15L8**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **15L8w**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		P*	P
Musculo-skeletal (Superficial)		P	P	P	P	P	P		P*	P
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **17L5**

Indications for Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		N	N	N		N	N	N	N*	N
Abdominal		N	N	N		N	N	N	N*	N
Intraoperative Abdominal		N	N	N		N	N	N	N*	N
Intraoperative Neurological		N	N	N		N	N	N	N*	N
Pediatric		N	N	N		N	N	N	N*	N
Small Organ (specify)**		N	N	N		N	N	N	N*	N
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N	N	N		N	N	N	N*	N
Laparoscopic										
Musculo-skeletal (Conventional)		N	N	N		N	N	N	N*	N
Musculo-skeletal (Superficial)		N	N	N		N	N	N	N*	N
Other (specify)***										

N=New Indication

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **V5M TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K052021, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **V7M TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **V7B TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal		P	P	P	P	P	P		P*	P
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **3V2c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P*	P
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **4V1**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		N*	N
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.
N=New Indication

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **4V1c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P*	P
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **4V2**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **5V2c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: 7V3c

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: 8V3

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, and #K032114.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **8V5**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**										
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **10V4**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Neurological		P	P	P	P	P	P		P*	P
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)**		P	P	P	P	P	P		P*	P
Neonatal Cephalic		P	P	P	P	P	P		P*	P
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)***		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

**small organs (breast, testes, thyroid, penis)

***neonatal cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: **AUX CW**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					P					
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel					P					
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, #K022567, #K002807, and #K973767.

Additional Comments:

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: Sequoia Ultrasound System

Transducer: **AcuNav (IC10V5 or 10F) Ultrasound Catheter**

Indications for Use: The AcuNav™ Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-luminal		P	P	P	P	P	P		P*	P
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K033650, #K033196, and #K992631.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K063085

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063085

Device Name: Sequoia Ultrasound System

Transducer: **AcuNav 8F Ultrasound Catheter**

Indications for Use: The AcuNav™ Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)**										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P*	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-luminal		P	P	P	P	P	P		P*	P
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (Intra-Cardiac)		P	P	P	P	P	P		P*	P

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, and #K042593.

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063085